

EXHIBIT A

FILED: NEW YORK COUNTY CLERK 09/24/2014 01:02 PM

INDEX NO. 159371/2014

NYSCEF DOC. NO. 1

RECEIVED NYSCEF: 09/24/2014

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

BRIAN O'CONNOR,

Index No.

Plaintiff(s),

Summons

-against-

SMITH & NEPHEW, INC.

Date Index No. Purchased:

Defendant(s).

To the above named Defendant(s)

SMITH & NEPHEW, INC.
CT Corporation
111 8th Avenue
New York, New York 10011

You are hereby summoned to answer the complaint in this action and to serve a copy of your answer, or, if the complaint is not served with this summons, to serve a notice of appearance, on the Plaintiff's attorney within 20 days after the service of this summons, exclusive of the day of service (or within 30 days after the service is complete if this summons is not personally delivered to you within the State of New York); and in case of your failure to appear or answer, judgment will be taken against you by default for the relief demanded in the complaint.

The basis of venue is Plaintiff resides in New York County
which is 7 East 14th Street, Apt. 19G, New York, New York 10003

Dated: New York, New York

September 24, 2014

TRIEF & OLK

by

Jordan Rutsky

Attorneys for Plaintiff

BRIAN O'CONNOR

150 East 58th Street
34th Floor
New York, New York 10155
e-mail: jrtusky@triefandolk.com
AND ryerman@triefandolk.com

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

-----X
BRIAN O'CONNOR,

Plaintiff,

- against -

SMITH & NEPHEW, INC.

Defendant.
-----X

Index No.:

Filed:

VERIFIED
COMPLAINT

Plaintiff Brian O'Connor, by his attorneys Trief & Olk, complaining of the defendant alleges as follows:

1. Plaintiff Brian O'Connor was at the time of the accident and at all times thereafter, a resident of New York County, New York.
2. Defendant Smith & Nephew, Inc. (hereinafter, "S&N") is a foreign corporation organized under the laws of Delaware, authorized to do business in the State of New York with its principal place of business in Memphis, Tennessee.
3. Upon information and belief, defendant S&N conducted business in the State of New York on or before July 31, 2009 until the present.
4. Upon information and belief, defendant S&N contracted to supply goods or services in the State of New York on or before July 31, 2009 until the present.
5. Upon information and belief, defendant S&N regularly does or solicits business or derives substantial revenue from goods used in the State of New York.

6. Prior to July 31, 2009, defendant S&N manufactured, designed, marketed and/or sold a product known as a PROMOS Inclination Set, Size 20 mm, Ref 42 180 (hereinafter, the "PROMOS Inclination Set").

7. On July 31, 2009, plaintiff Brian O'Connor underwent surgery during which a PROMOS Inclination Set, bearing Lot number A0803483, was implanted in his shoulder as part of a left shoulder hemiarthroplasty. The Implant Log for the surgery, which confirms that a PROMOS Inclination Set bearing Lot number A0803483 was implanted in the plaintiff, is annexed as Exhibit A.

8. The PROMOS Inclination Set implanted in plaintiff Brian O'Connor on July 31, 2009 was manufactured by S&N.

9. The PROMOS Inclination Set implanted in plaintiff Brian O'Connor on July 31, 2009 was designed by S&N.

10. The PROMOS Inclination Set implanted in plaintiff Brian O'Connor on July 31, 2009 was marketed by S&N.

11. The PROMOS Inclination Set implanted in plaintiff Brian O'Connor on July 31, 2009 was sold by S&N.

12. On or about April 7, 2010, defendant S&N issued a recall covering all lots of the PROMOS Inclination Set. The recall, as published on the Food and Drug Administration website, is annexed as Exhibit B.

13. The April 7, 2010 recall was issued due to complaints of Inclination Set screws fracturing.

14. The April 7, 2010 recall included the PROMOS Inclination Set implanted in the plaintiff on July 31, 2009.

15. After plaintiff's July 31, 2009 surgery, he developed pain and other unforeseen sequelae.

16. On May 30, 2014, during exploratory surgery required to repair the shoulder, it was discovered that a screw which is part of the PROMOS Inclination Set implanted in the plaintiff had fractured.

17. The issue with the PROMOS Inclination Set implanted in the plaintiff, i.e., the fractured screw, was the same defect for which the recall was issued on April 7, 2010.

18. As a result of the fracture of the PROMOS Inclination Set implanted in the plaintiff and caused by it, plaintiff suffered severe and permanent injuries.

AS AND FOR A FIRST CAUSE OF ACTION

19. Plaintiff repeats and realleges all of the allegations in all preceding paragraphs of the complaint as though fully alleged herein.

20. Defendant S&N defectively designed the PROMOS Inclination Set implanted in the plaintiff such that its screw was subject to and did fracture.

21. Plaintiff's severe injuries were caused by defendant S&N's defective design of the PROMOS Inclination Set.

AS AND FOR A SECOND CAUSE OF ACTION

22. Plaintiff repeats and realleges all of the allegations in all preceding paragraphs of the complaint as though fully alleged herein.

23. Defendant S&N defectively manufactured the PROMOS Inclination Set implanted in the plaintiff such that its screw was subject to and did fracture.

24. Plaintiff's severe injuries were caused by defendant's defective manufacture of the PROMOS Inclination Set.

AS AND FOR A THIRD CAUSE OF ACTION

25. Plaintiff repeats and realleges all of the allegations in all preceding paragraphs of the complaint as though fully alleged herein.

26. Plaintiff's severe injuries were caused by breaches of warranties by the defendant.

AS AND FOR A FOURTH CAUSE OF ACTION

27. Plaintiff repeats and realleges all of the allegations in all preceding paragraphs of the complaint as though fully alleged herein.

28. The defendant S&N was negligent.

29. Plaintiff was caused to suffer severe injury due to the negligence of the defendant.

WHEREFORE, plaintiff demands judgment against the defendant S&N in a monetary sum far exceeding the jurisdictional limitations of all lower courts of the State of New York which would otherwise have jurisdiction over this action, as follows:

- (a) on the first claim for relief, compensatory damages together with interest, costs and disbursements as provided by law; and
- (b) on the second claim for relief, compensatory damages together with interest, costs and disbursements as provided by law; and
- (c) on the third claim for relief, compensatory damages together with interest, costs and disbursements as provided by law; and

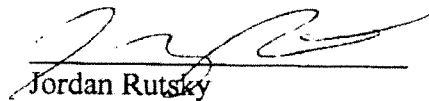
(c) on the fourth claim for relief, compensatory damages together with interest, costs and disbursements as provided by law; and

(d) such other and further relief as this court deems proper.

Dated: New York, New York
September 24, 2014

TRIEF & OLK

By:



Jordan Rutsky
Attorneys for Plaintiff
150 East 58th Street
New York, New York 10155
(212) 486-6060

VERIFICATION

STATE OF NEW YORK)
 ss:
COUNTY OF NEW YORK)

BRIAN O'CONNOR, being duly sworn, deposes and says:

Deponent is the plaintiff in the within action. Deponent has read the foregoing **Complaint** and knows the contents thereof; that the same is true to deponent's own knowledge, except as to those matter therein stated to be alleged on information and belief, and that as to those matters deponent believes them to be true.


Brian O'Connor

Sworn to before me this
24 day of September, 2014


Notary Public

JORDAN KYLE RUTSKY
Notary Public, State of New York
No. 02RU6305648
Qualified in New York County
Commission Expires June 8, 2018

FILED: NEW YORK COUNTY CLERK 09/24/2014 01:02 PM

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NYSCEF DOC. NO. 2

RECEIVED NYSCEF: 09/24/2014

EXHIBIT A



Saint Vincent
Catholic Medical
Centers

ST. VINCENT'S - MANHATTAN

O'CONNOR, BRIAN H
0859928 133871400
PAE, ROBERT AMS
07/31/09 NOR H
M 01/25/1953 56Y Z K05

IMPLANT LOG

Date:

7/31/09

Surgeon:

Dr. Pae

Procedure:

ORIF Left proximal humerus

Circ. Nurse:

S. Lee / S. Jones / R. Rouse



Plus Orthopedics AG
CH-6343 Rotkreuz - Switzerland

STERILE R CE 0123

V. PROMOS®
Humeral Stem

C 2015/04 REF 42 019

S LOT E0800465

non-cemented

1.5

T8A14V



(01)07611996084672(17)150410(10)E0800465

Vendor/Manufacturer:

Catalog/Model #:

Serial/Log #:

Description:

Expiration Date:



Plus Orthopedics AG
CH-6343 Rotkreuz - Switzerland

STERILE R CE 0123

V. PROMOS®
Body

C 2014/11 REF 42 160

S LOT A0707628

30mm

T8A14V



(01)07611996083620(17)141101(10)A0707628

Vendor/Manufacturer:

Catalog/Model #:

Serial/Log #:

Description:

Expiration Date:



Plus Orthopedics AG
CH-6343 Rotkreuz - Switzerland

STERILE R CE 0123

V. PROMOS®
Inclination Set

C 2015/07 REF 42 180

S LOT A0803483

20mm

T8A14V



(01)07611996083651(17)150703(10)A0803483

Vendor/Manufacturer:

Catalog/Model #:

Serial/Log #:

Description:

Expiration Date:



Plus Orthopedics AG
CH-6343 Rotkreuz - Switzerland

STERILE R CE 0123

V. PROMOS®
Humeral Head

C 2015/04 REF 42 035

S LOT D0711157

R23/+7

CoCrMo



(01)07611996037807(17)150408(10)D0711157

Vendor/Manufacturer:

Catalog/Model #:

Serial/Log #:

Description:

Expiration Date:

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NYSCEF DOC. NO. 3

RECEIVED NYSCEF: 09/24/2014

EXHIBIT B

FDA Home³ Medical Devices⁴ Databases⁵

Class 2 Device Recall PROMOS Inclination set



510(k)⁷ De Novo⁸ Registration & Listing⁹ Adverse Events¹⁰ Recalls¹¹ PMA¹² Classification¹³ Standards¹⁴
 CFR Title 21¹⁵ Radiation-Emitting Products¹⁶ X-Ray Assembler¹⁷ Madsen Reports¹⁸ CLIA¹⁹ TPLC²⁰ Inspections²¹

New Search

[Back to Search Results](#)Class 2 Recall
PROMOS Inclination set

Date Posted	April 07, 2010
Recall Status ¹	Terminated on April 10, 2012
Recall Number	Z-1239-2010
Recall Event ID	54891 ²³
Premarket Notification 510(K) Number	K063578 ²⁴
Product Classification	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented ²⁵ - Product Code KWS ²⁶
Product	PROMOS Inclination set, SIZE 20mm, REF 42 180, S&N 75006722, QTY: (1), STERILE R, Smith & Nephew Orthopaedics AG, CH-Rotkreuz-Switzerland. The device is used as a semi-constrained, metal/polymer cemented shoulder prosthesis.
Code Information	All lots.
Recalling Firm/ Manufacturer	Smith & Nephew Inc 1450 E. Brooks Rd Memphis, Tennessee 38116
Consumer Instructions	Contact the recalling firm for information
For Additional Information Contact	Victor Rocha 901-399-6771
Manufacturer Reason for Recall	Firm received complaints of Inclination Set Screws fracturing.
FDA Determined Cause ²	DESIGN: Device Design
Action	All affected Smith & Nephew Sales Representatives were notified of problem and the recall overnight mail on January 23, 2009. All affected Smith & Nephew International Distributors were notified via email and telephone on January 23, 2009. They were instructed to immediately quarantine the product for return to Stericycle, Inc., 2670 Executive Dr. Suite A Indianapolis IN 46241. Direct questions to Smith & Nephew Inc. by calling 1-901-399-6153.
Quantity in Commerce	1,597 units
Distribution	Worldwide Distribution: United States, Australia, Austria, Belgium, China, Denmark, France, Germany, Greece, Great Britain, Italy, Netherlands, Poland, Portugal, Spain, Sweden and Switzerland.
Total Product Life Cycle	TPLC Device Report ²⁷

¹ For details about termination of a recall see Code of Federal Regulations (CFR), Title 21 § 2.55²⁸² Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.510(K) Database 510(K)s with Product Code = KWS and Original Applicant = PLUS ORTHOPEDICS AG²⁹

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22. <http://www.fda.gov/safety/recalls/enforcementreports/default.htm>
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=54891
24. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K063578>
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28. </scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=7.55>
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=KWS&applicant=PLUS%20ORTHOPEDICS%20AG

Page Last Updated: 09/22/2014

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.


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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph: 1-888-INFO-FDA (1-888-463-6332)
Email FDA

U.S. Gov. 

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive

 U.S. Department of Health & Human Services

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20. /scripts/cdrh/cfdocs/cfTPLC/tpic.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
22. <http://www.fda.gov/safety/recalls/enforcementreports/default.htm>
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=54891
24. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K063578
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=KWS
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=KWS
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29. /cfPMN/pmn.cfm?start_search=1&productcode=KWS&applicant=PLUS%20ORTHOPEDICS%20AG

AFFIDAVIT OF SERVICE THROUGH THE SECRETARY OF STATE

Index # 159371/14

Purchased/Filed: September 24, 2014

STATE OF NEW YORK

SUPREME COURT

NEW YORK COUNTY

Brian O'Connor

Plaintiff

against

Smith & Nephew, Inc.

Defendant

STATE OF NEW YORK
COUNTY OF ALBANY

SS.:

Heather Morigerato, being duly sworn, deposes and says: deponent is over the age of eighteen (18) years; that on September 29, 2014, at 11:45 am, at the office of the Secretary of State of the State of New York in the City of Albany, New York deponent served the annexed Notice of Commencement of Action Subject to Mandatory Electronic Filing with Summons and Verified Complaint and Supporting Exhibits on Smith & Nephew, Inc., the

Defendant in this action, by delivering to and leaving with Nancy Dougherty, AUTHORIZED AGENT in the Office of the Secretary of State, of the State of New York, personally at the Office of the Secretary of State of the State of New York, 2 true copies thereof and that at the time of making such service, deponent paid said Secretary of State a fee of 40 dollars; That said service was made pursuant to Section 306 Business Corporation Law.

Deponent further says that deponent knew the person so served as aforesaid to be the agent in the Office of the Secretary of State of the State of New York, duly authorized to accept such service on behalf of said defendant.

Description of the person served: Approx. Age: 55 Approx. Wt: 130lbs Approx. Ht: 5'3"Color of skin: White Hair color: Black Sex: Female Other: _____

Sworn to before me on this

29th day of September, 2014

SCOTT SCHUSTER
NOTARY PUBLIC, State of New York
NO. 01SC8308636, Albany County
Commission Expires July 28, 2018

Heather Morigerato
Heather Morigerato
Attny's File No.

Invoice/Work Order # SP1411929

SERVICO, INC. - PO Box 871 - ALBANY, NEW YORK 12201 - PH 518-463-4179

EXHIBIT B

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BRIAN O'CONNOR,

Plaintiff,

v.

SMITH & NEPHEW, INC.,

Defendant.

**NOTICE OF REMOVAL TO ALL
ADVERSE PARTIES**

Case No. _____

TO: Jordan Rutsky, Esq.
TRIEF & OLK
150 East 58th Street, 34th Floor
New York, NY 10155
(212) 486-6060


Attorney for Plaintiff

PLEASE TAKE NOTICE, that on October 22, 2014, Defendant Smith & Nephew, Inc. filed a Notice of Removal of this action to the United States District Court for the Southern District of New York. A true and correct copy of the Notice of Removal is annexed hereto.

This Notice is served upon you as counsel of record for Plaintiff in compliance with 28 U.S.C. § 1446.

Dated: October 22, 2014

By: _____


Glenn S. Kerner, Esq.
Nilda M. Isidro, Esq.
Carla Rose Karp, Esq.
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, New York 10018
(212) 813-8800
gkerner@goodwinprocter.com
nisidro@goodwinprocter.com
ckarp@goodwinprocter.com

*Attorneys for Defendant
Smith & Nephew, Inc.*

EXHIBIT C

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

BRIAN O'CONNOR,

Plaintiff,

v.

SMITH & NEPHEW, INC.,

Defendant.

**NOTICE OF FILING
OF NOTICE OF REMOVAL**

Index No. 159371/14

To: The Clerk of the Court
Supreme Court of the State of New York
County of New York

PLEASE TAKE NOTICE, that on October 22, 2014, Defendant Smith & Nephew, Inc. filed a Notice of Removal of this action to the United States District Court for the Southern District of New York. A true and correct copy of the Notice of Removal is annexed hereto.

PLEASE TAKE FURTHER NOTICE that the filing of the Notice of Removal in the United States District Court for the Southern District of New York and the filing of this Notice effect the removal of this action, and pursuant to 28 U.S.C. § 1446(d), the above-captioned action may proceed no further unless and until the case is remanded.

Dated: October 22, 2014

By: /s/ Carla Rose Karp
Glenn S. Kerner, Esq.
Nilda M. Isidro, Esq.
Carla Rose Karp, Esq.
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, New York 10018
(212) 813-8800
gkerner@goodwinprocter.com
nisidro@goodwinprocter.com
ckarp@goodwinprocter.com

*Attorneys for Defendant
Smith & Nephew, Inc.*

AFFIRMATION OF SERVICE

I hereby affirm that on October 22, 2014, I caused true and correct copies of the forgoing to be served by electronic means, via the New York State Courts Electronic Filing system (“NYSCEF”), on all counsel of record registered to receive electronic notices.

/s/ Carla Rose Karp
Carla Rose Karp